UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,032	01/03/2007	Kyogo Itoh	3691-0128PUS1	4420

2292 7590 02/04/2011

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
02/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,032	ITOH ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 0201 and 27 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *8-14 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15,16 and 18* is/are rejected.

7)☒ Claim(s) *15, 16, 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/22/2006, 7/31/2006, 3/14/2008, 5/28/2009, and 10/27/2010.

DETAILED ACTION

This action is responsive to communication filed 4/26/2010 and 10/27/2010.

Claims 1-4, 15, 16 and 18 are under current examination.

Given the rejections below, no additional species were searched.

Information Disclosure Statement

It is noted here that a number of references were lined through and not initialed on the IDS filed 3/22/2006. These references are foreign references and no English translation or description of the pertinent information was provided.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4/26/2010 is acknowledged. The traversal is on the ground(s) that that the applied PCT publication does not render the claimed invention anticipated or obvious and there is no evidence that examination of all of the Groups would lead to undue burden. This is not found persuasive because as indicated in the restriction requirement, para. 3, the groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: WO1994/20127 (see IDS) provides HCV immunogenic peptides with HLA-A2 binding motifs including the sequence set forth by SEQ ID NO: 1 and this peptide is encompassed by the instant claims. It is further noted that the peptide set forth by SEQ ID NO: 2 is also known in the prior art; see rejections below. Thus, the special technical feature of Group I cannot be a special technical feature under PCT Rule 13.2 because the technical feature is shown in the prior art. Each group of Groups

I-VI requires a technical feature that is not required by any of the other groups. Thus, the restriction set forth in the Office action mailed out 2/26/2010 is proper based on PCT Rule 13.2.

In response to Applicant's traverse to the species election, according to PCT Rule 13.2 and to the guidelines **in Section (f)(i)(B)** of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a **common structure**. According to PCT Rule 13.2 and to the guidelines **in Section (f)(i)(A) of Annex B** of the PCT Administrative Instructions, all alternatives of a Markush Group must have **a common property or activity**. In the present case, SEQ ID NO: 1-8, 16, 20 and 38 recited in the claims are not regarded as being of similar nature because all the alternatives do not share either a common structure or same functions. Therefore, these species do not relate to a single general inventive concept under PCT Rule 13.1 and PCT Rule 13.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-14 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/26/2010.

Applicant elected Group I and species SEQ ID NO: 2 and HLA-A24 and claims 1-4, 15, 16 and 18 read on the elected SEQ ID NO:2, or are generic thereto.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least p. 37.

The use of the trademarks LUMIPULSE, LUMINEX and TWEEN have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that LUMIPULSE, LUMINEX and TWEEN are merely examples and all trademarks found throughout the specification should be properly addressed. See at least Example 3.

Claim Objections

Claims 15 and 18 are objected to because of the following informalities: the claims do not have “and” between items f) and g).

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 15, 16 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims (in part) are directed to a peptide derived from HCV. This does not read on the involvement of the hand-of-man and as claimed, the peptide is not required to be isolated or purified. Thus, such a peptide encompasses those that are found in nature, including within the blood of an HCV-infected human subject. It is noted that claims 15, 16 and 18 read upon a pharmaceutical composition, including a HCV vaccine, and a kit comprising such a peptide. However, the claims do not indicate the involvement of the hand-of-man or that the composition may comprise other ingredients which would indicate the involvement of the hand-of-man (e.g. an adjuvant, pharmaceutically acceptable carrier, microcarriers, etc.).

It is suggested that Applicant at least inserts a descriptive term for the peptide such as “isolated” or “purified”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5-7, 15, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to (in part): a peptide which has an amino acid sequence “represented” by any one of SEQ ID NOs: 1-8, 16, 20 and 38; see claim 2, line 2 as a

representative claim. It is not clear what is meant by the term "represented" and whether such a term means that claimed peptide comprises any one of the sequences set forth by SEQ ID NOs: 1-8, 16, 20 and 38 or that the claimed peptide comprises various embodiments of any one of the sequences set forth by SEQ ID NOs: 1-8, 16, 20 and 38, such as a dipeptide, or variants, homologues etc. thereof.

For purposes of this action, the claims will be interpreted as a peptide which comprises any one of the sequences set forth by SEQ ID NOs: 1-8, 16, 20 and 38 and variants, homologues etc. thereof.

Dependent claims fall herein.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 15, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to (in part): a peptide derived from HCV comprising an HLA-binding motif in its sequence and is capable of being recognized by an antibody detected in a patient with HCV infection; see claim 1 as a representative. Separately,

some claims are directed to such a peptide which has an amino acid sequence having a homology of at least 70% with any one of the sequences set forth by SEQ ID NOs: 1-8, 16, 20 and 38; see at least claim 3. Claim 18 is directed to a kit with the intended use of predicting the prognosis of HCV infection comprising any peptide derived from HCV (see part a) or any peptide having an amino acid sequence having a homology of at least 70% with the sequence set forth by SEQ ID NOs: 1-8, 16, 20 and 38. Note that, as discussed above, the claims are interpreted to read upon peptides which may be "represented" by variants and homologues thereof.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a

known or disclosed non-functional characteristic (structure) that correlates to the function.

This rejection is based upon three grounds.

First, as noted above, the claims are directed to a peptide derived from HCV comprising an HLA-binding motif in its sequence which is capable of being recognized by an antibody detected in a patient with an HCV infection. Note that the antibody as claimed may be *any* antibody present/detected in an HCV-infected patient and such an antibody is not necessarily limited to that which is associated to an HCV infection. Further, as claimed, the antibody may be detected in both a healthy subject and an HCV-infected subject. While the antibody may be of any structure, the claim functionally requires that the HCV peptide is recognized by such an antibody.

The instant specification states that a plurality of HCV peptides were found that highly reacted with IgG in the blood from HCV-infected patients, in contrast to sera from healthy donors, which rarely reacted to these peptides; see para. [0095]. The specification provides written description for *some* specific HCV-related antibodies which are shown to recognize HCV peptides; see para. [0095] disclosing the detection of an antibody against an HCV peptide. However, the instant specification fails to describe any structure to function correlation for any antibody that is unrelated to an HCV infection as so broadly claimed.

Secondly, as noted above, some of the claims are directed to (in part) a peptide which has an amino acid sequence having a homology of at least 70% with any one of the sequences set forth by SEQ ID NOs: 1-8, 16, 20 and 38; see at least claim 3. As

claimed, the claims are directed to any and all peptides that are derived from HCV having a homology of at least 70% with any one of the sequences set forth by the claimed SEQ ID NOs. Such a genus allows for a 30% difference, a difference not adequately described by the instant specification in view of the specific sites among the peptide where the difference may be tolerated or specific amino acids that may be replaced or inserted. Functionally, the claims require that the amino acid sequence is capable of being recognized by a broad genus of antibodies that is not necessarily related to an HCV infection. Also see claim 18 which requires that a peptide is used for the function of predicting the prognosis of an HCV infection. However, the specification fails to provide any structural support for the genus of peptides and/or antibodies that would lead to the claimed function (peptide-antibody recognition). The instant specification fails to describe the 30% difference in sequence structure that would be tolerated so that the claimed function can occur. Also, the claims are directed to (in part) a peptide which “represented” by the claimed sequences; see claim 1. Given the broadest, reasonable interpretation, the claims may be directed to variants and/or homologues of such sequences. However, the instant specification provides no adequate description for such a genus of peptides.

Lastly, as noted above, claim 18 is directed to a kit with the intended use of predicting the prognosis of an HCV infection comprising any peptide derived from HCV (see part a) or any peptide having an amino acid sequence having a homology of at least 70% with the sequence set forth by SEQ ID NOs: 1-8, 16, 20 and 38 (see parts b and c). And, comparable to the discussion above, the claim is drawn to a genus of

peptides, including those that are of at least 70% homologous with the claimed SEQ ID NOs.

The instant specification fails to describe a genus of peptides, including some structural feature of the genus that would successfully lead to the prediction of the prognosis of an HCV infection as claimed. Instead, the specification identifies a single peptide, NS5A-2132 or SEQ ID NO: 2, wherein detection of the antibody to which this peptide binds correlates with the prognosis of an individual infected with HCV. However, this is not true for all peptides as described by the instant specification. For example, the instant specification states that detection of the anti-C-35 antibody does not correlate with such a prognosis; see p. 52. Separately, it is expected that peptides of differential structures would lead to different functions; the required structures of the peptide that would lead to this specific function set forth by the claims is not described by the specification.

It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. It is known in the art that the substitution of some amino acids within the protein sequence may cause the loss of function of the protein. Thus, the large number of sequences encompassed by the current claims may or may not be effective in being capable of being recognized by an antibody or HLA A2 or HLA-A24 restricted cytotoxic T cell or useful in predicting the prognosis of an HCV infection. See the following publications that support this unpredictability (Baker et al., Protein Structure Predication and Structural Genomics, Science (2001) Vol. 294, No. 5540,

pages 93- 96; Attwood, T. The Babel of Bioinformatics, Science (2000) Vol. 290, no. 5491, pages 471-473). The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

In view of the lack of structure to function correlations and lack of predictability in such correlations, the claims are rejected for lacking adequate written description by the instant specification.

Claims 15, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition or a composition used for detection or a method of predicting the prognosis of an HCV infected subject using one peptide, does not reasonably provide enablement for a *pharmaceutical* composition, a *vaccine* or a method of predicting the prognosis of an HCV infected subject using any and all peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Claims 15 and 16 are drawn to (in part) a pharmaceutical composition or a vaccine comprising the peptides of a, b, c, d or e; see claim 15. Claim 18 is directed to (in part) a

kit of predicting the prognosis of HCV infection comprising at least one of the peptides of a, b, c, d or e as claimed.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C 112 ¶, the courts have put forth a series of factors. The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

Because the claim 15 and 16 read on a pharmaceutical composition and/or a vaccine, they implicitly require that the claimed intended use be enabled as effective treatment. See attached document which provides the meaning of a *vaccine* defined as a prophylactic or therapeutic material containing antigens derived from one or more pathogenic organisms which, on administration to a subject, will stimulate active immunity and protection against infection with these or related organisms.

The instant specification describes the administration of HCV peptides and the attenuation of HCV RNA following such administration; see Ex. 5, Figures 33 and 34 and para. [0150]. However, the data presented in Figures 33 and 34 show a wide range of fluctuations between increases and decreases in HCV-RNA over time and it is not

clear further values over longer timelines would lead to protection against infection (e.g. the amount of HCV-RNA at 6 months, 2 years, 4 years etc). Note that some attenuation of HCV RNA is not equivalent to an effective pharmaceutical composition and/or vaccine.

The art teaches that, to date, there are no prophylactic or effective therapeutic treatments against HCV infection. See Rollier et al. (J. Virol. 78: 187-196, p. 187); Huang et al. (Antivir. Res. 71: 351-62, at 351); each disclosing that there are currently no anti-HCV vaccines and that the most effective treatments involve composition not comprising HCV antigens). These references teach that despite the years of attempts to develop such a vaccine, those in the art have been hampered from doing so by several difficulties. See e.g., Rollier, at 187; Berzofsky et al., J Clin Invest 114: 452-62, at 450 and 456-7).

Further, the failure to develop HCV vaccines and therapies have occurred despite the abundance of references through the past 10 years teaching the efficacy of HCV antigens in eliciting humoral and cellular immune response in several infection models. See e.g., Shirai et al., J Virol, 68: 3334-42; and Koziel et al., J Virol, 67: 7522-32. Although the art indicates that there has been recent progress in the art (Berzofsky, page 456; and Tan et al., Curr Opin Pharmacol 4: 465-70, at 468), these teachings do not teach that any peptide vaccine would be capable of achieving the claimed results. Rather, the Tan reference indicates that the most effective vaccines comprise full length E 1 or anti-HCV monoclonal antibodies, and that such vaccines have still proven unable to prevent infection. Id. Moreover, even recent teachings in the art indicate that the

"determinants of immunity towards HCV are unknown" and indicate that if anti-HCV vaccines are made, they are likely not to be peptides based vaccines. See e.g., Racanelli et al., Clin Immunol 125: 5-12, at pages 6 (left column) and 10 (right column). From these teachings, it would therefore appear that the art of treating and preventing HCV infection is wrought with complexity and unpredictability

Claim 18 is directed to (in part) a kit of predicting the prognosis of HCV infection comprising at least one of the peptides of a, b, c, d or e as claimed. The specification identifies a single peptide, NS5A-2132 or SEQ ID NO: 2, wherein detection of the antibody to which this peptide binds correlates with the prognosis of an individual infected with HCV. However, this is not true for all peptides as described by the instant specification. For example, the instant specification states that detection of the anti-C-35 antibody does not correlate with such a prognosis; p. 52. While the claim is broadly directed to a genus of peptides of differential structures (e.g. length, structural sequences etc), it is expected that peptides of such differential structures and properties would lead to different functions; the required structures of the peptide that would lead to this specific function set forth by the claims is not described by the specification and one of ordinary skill in the art would be required to further identify which peptides would and would not work for the intended use of the invention (undue experimentation). As discussed above, the prior art teaches that such changes in structure may lead to changes in function and such changes are unpredictable.

The claims are rejected as lacking enablement in view of at least the scope of the claims, the lack of predictability and prior art teachings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Battegay et al. (*J. of Virology*, 1995-see IDS).

The claims are drawn to (in part): a peptide derived from HCV comprising an HLA-binding motif in its sequence which is capable of being recognized by an antibody detected in a patient with HCV infection; see claim 1.

Battegay discloses a number of HCV peptides found in patients with an HCV infection, meeting the claim limitation of “a peptide derived from hepatitis C virus” (see at least title and abstract); note that Battegay discloses the sequence set forth by SEQ ID NO: 1 of the instant specification which comprises the following sequence YLLPRRGRRL. See Table 5, p. 2465 and instant claims 2 and 3. The authors further describe this HCV core peptide as possessing HLA-A2 binding properties; see Table 5 for the IC50 value, and instant claims 1 and 4, in part, which is directed to "an HLA-binding motif" and "an HLA-A2 or HLA-A24-restricted cytotoxic T cell". Given Battegay describes the same structure of this peptide set forth by SEQ ID NO: 1, it must also meet the limitation of “being recognized by an antibody detected in a patient with hepatitis C virus infection” of claim 1 because a chemical and its properties are inseparable. See MPEP 2112.01, II for “If the composition is physically the same, it

must have the same properties". Note that this reference also meets claims 5, part a (at least), 6, 7, 15, part a (at least), 16 and 18, part a (at least) which are directed to (in part) "a peptide derived from hepatitis C virus according to claim 1". It is noted here that claims 15, 16 and 18 are directed to a "pharmaceutical composition", "vaccine", or "a kit for diagnosing hepatitis C virus infection or predicting the prognosis of hepatitis C virus infection" and such recitations are considered the intended use(s) of the product claims. Of note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, the claim is met. In this case, since the prior art teaches the same peptide as claimed, it must be capable of performing the same intended use.

Thus, the prior art meets the rejected claims above.

Claims 1-7, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Donnelly et al. (US Patent 6653125-see IDS).

Donnelly describes various proteins derived from NANBV (or "non-A, non-B hepatitis" or the hepatitis C virus; see title, col. 1, lines 44). Donnelly provides a polypeptide which comprises the sequence set forth by SEQ ID NO: 2 (elected species) by the instant specification; see SEQ ID NO: 50, residues 119-127 for RYAPACKPL and instant claims 2 and 3. Given Donnelly describes the same structure of this peptide set forth by SEQ ID NO: 2, it must also meet the limitation of "being recognized by an antibody detected in a patient with hepatitis C virus infection" of claim 1 because a

chemical and its properties are inseparable. See MPEP 2112.01, II for “If the composition is physically the same, it must have the same properties”. Note that this reference also meets claims 5, part a (at least), 6, 7, 15, part a (at least), 16 and 18, part a (at least) which are directed to (in part) “a peptide derived from hepatitis C virus according to claim 1”. It is also noted that claims 15, 16 and 18 are directed to a “pharmaceutical composition”, “vaccine”, or "a kit for diagnosing hepatitis C virus infection or predicting the prognosis of hepatitis C virus infection" and such recitations are considered the intended use(s) of the product claims. Of note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, the claim is met. In this case, since the prior art teaches the same peptide as claimed, it must be capable of performing the same intended use.

It is noted here that the instant specification provides that the “term” peptide includes the term “polypeptide”; see para. [0066].

Thus, the prior art meets the rejected claims above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 15, 16 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 12/223062. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a HCV-derived peptide or compositions comprising such set forth by SEQ ID NO: 1, YLLPRRGPRL.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648